

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION**

Kathy Giannone and Blase Giannone,)	
individually and as guardian of their minor)	
child J. G.,)	
)	Case No.
Plaintiffs,)	
)	
v.)	JURY TRIAL DEMANDED
)	
Dixie Dew Products, Inc.,)	
)	
Defendant.		

COMPLAINT

Plaintiffs, Kathy Giannone and Blase Giannone, individually and as guardians of their minor child, J. G., by and through their attorneys of record, Jeffrey M. Goldberg Law Offices and Robins Cloud LLP, and for their causes of action against Dixie Dew Products, Inc. ("Defendant"), states and alleges as follows:

PARTIES

1. At all times relevant to this action, Plaintiffs resided in Manatee County, Florida, with minor child J. G. Plaintiffs Kathy Giannone and Blase Giannone are the natural parents of J. G. Plaintiffs are citizens of the State of Florida.
2. At all times relevant to this action, Defendant, Dixie Dew Products, Inc., was a Kentucky corporation with its principal place of business located at 1360 Jamike Ave., Erlanger, KY 41018. Dixie Dew Products is a citizen of the State of Kentucky. At all times relevant to this action, Dixie Dew Products, Inc., was a manufacturer, distributor, and/or seller of a wide-variety of food stuffs and other custom manufactured products, including the SoyNut Butter products subject to this action, to customers across the country, including The SoyNut Butter Company in Illinois.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 USC § 1332(a) because the matter in controversy exceeds \$75,000, exclusive of costs and it is between citizens of different states (Kentucky and Florida). Further, Defendant Dixie Dew Products, Inc. contracted with The SoyNut Butter Company (an Illinois resident) to produce and provide the food product at issue to The SoyNut Butter Company, thereby purposefully availing itself of the Illinois marketplace.

4. Venue in the United States District Court for the Northern District of Illinois is proper pursuant to 28 USC § 1391(a)(1) and (2) because Dixie Dew Products, Inc. is subject to personal jurisdiction in this judicial district at the time of the commencement of the action, and because a substantial part of the events or omissions giving rise to the Plaintiff's claims and causes of action occurred in this judicial district.

FACTS

The Outbreak

5. The FDA and the CDC, along with state and local health officials, investigated an outbreak of Shiga toxin-producing *E. coli* O157:H7 infections linked to the consumption of I.M. Healthy brand SoyNut Butter products manufactured, distributed, and/or sold by The SoyNut Butter Company of Glenview, Illinois from March 3, 2017 through May 4, 2017. According to the CDC, as of May 4, 2017, a total of 32 people infected with the outbreak strain of *E. coli* O157:H7 were reported from 12 states. The number of ill people identified in each state is as follows: Arizona (4), California (5), Florida (2), Illinois (1), Massachusetts (1), Maryland (1), Missouri (1), New Jersey (1), Oregon (11), Virginia (2), Washington (2), and Wisconsin (1).

6. Twelve ill people have been hospitalized, and 9 people developed hemolytic uremic

syndrome (HUS), a potentially life-threatening type of kidney failure. Twenty-six of the 32 illnesses were reported in children under the age of 18. No deaths have been reported. Known illnesses started on dates ranging from January 6, 2017 to April 18, 2017.

7. The epidemiologic evidence available to investigators at this time indicates that I.M. Healthy SoyNut Butter products are a source of the outbreak. In interviews conducted by state and local health department officials, ill people or their family members answered questions about the foods they ate and other exposures in the week before they became ill. Fifteen people reached for interviews reported eating I.M. Healthy brand SoyNut Butter products at home (9 people) in the week before they became ill, attending a facility that served I.M. Healthy brand SoyNut Butter (2 people), or attending childcare centers that served I.M. Healthy brand SoyNut Butter and I.M. Healthy brand granola coated with SoyNut Butter (4 people).

8. On March 2, 2017, the FDA and CDC held a call with the owners of The SoyNut Butter Company to advise the firm about the multistate outbreak linked to their SoyNut Butter products.

9. CDC recommends that consumers not eat, and childcare centers and other institutions not serve, any variety or size of I.M. Healthy brand SoyNut Butter or I.M. Healthy brand granola coated with SoyNut Butter produced by The SoyNut Butter Company. The CDC also urges consumers to check their pantry for SoyNut Butter products.

10. The SoyNut Butter Company announced a voluntary recall of I.M. Healthy Original Creamy SoyNut Butter with the “Best By” date of 08-30-18 or 08-31-18. The voluntary recall is in response to the FDA alerting us of a possible link between our product and illnesses regarding *E. coli*. Consumers who have purchased I.M. Healthy Original Creamy SoyNut Butter should not consume the product.

11. On March 4, 2017, The SoyNut Butter Company announced an expansion of its voluntary

recall to include individual cups with “Best By” date of 08-08-18; 4 pound tubs with Best By dates at 11-16-18 and 07-25-19; and 15 ounce jars 07-05-18, 08-30-18 and 08-31-18.

12. On March 7, 2017, The SoyNut Butter Company announced a second expansion of its voluntary recall. This expansion included recalls of all “Best Buy” dates of I.M. Healthy SoyNut Butters and I.M. Healthy Granola. These products include: I.M. Healthy SoyNut Butter packaged in 15 ounce plastic jars, individual portion cups, 4 pound plastic tubs or 45 pound pails. SoyNut Butter in Original Creamy, Chunky, Honey Creamy, Unsweetened, and Chocolate. I.M Healthy Granola packaged in individual serving packages, 12 ounce bags, 50 ounce bags, and 25 pound bulk bag. I.M. Healthy Granola in Original, Apple, Blueberry, and Raisin and Cranberry.

13. The recall expanded in the United States to include Dixie Diner’s Club Brand Carb Not Beanit Butter and 20/20 Lifestyle Yogurt Peanut Crunch Bars.

14. The SoyNut Butter Company announced on its website that it has a third party contract company, Dixie Dew Products, Inc., who manufactures its products.

15. From March 3, 2017 through March 15, 2017, the FDA conducted a series of health inspections on Dixie Dew Products, Inc. During these inspections, the FDA found “grossly insanitary conditions” and multiple violations of critical food safety procedures. Some of such violations include, but are not limited to:

- a. “Failure to manufacture and package foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination”;
- b. “All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source”;
- c. “Hand-washing facilities lack running water of a suitable temperature”;
- d. “Failure to maintain equipment in an acceptable condition through appropriate cleaning

and sanitizing”;

- e. “Employees did not wash hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated”;
- f. “Failure to perform microbial testing where necessary to identify possible food contamination”;
- g. “The plant is not constructed in such a manner to allow floors and ceilings to be adequately cleaned and kept clean and kept in good repair”;
- h. “Failure to provide adequate ventilation to minimize odors and vapors in areas where they may contaminate food”;
- i. “Effective measures are not being taken to exclude pests from the processing areas”; and
- j. “Failure to remove litter and waste that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures”.

16. As a result of the FDA’s findings, on March 27, 2017, the FDA suspended operations at Dixie Dew Products, Inc.’s facility in Erlanger, Kentucky. The Suspension Order cites that the “FDA has determined that food manufactured, processed, packed, received, or held by your facility has a reasonable probability of causing serious adverse health consequences or death to humans.” The Suspension Order further confirms the presence of insanitary conditions at Dixie Dew Products, Inc.’s facility and fecal coliform bacteria in unopened jars of products. Further, the FDA found that Dixie Dew Products, Inc. did not calibrate their thermometer used to measure and verify the adequacy of their kill step.

17. The Suspension Order concludes that “[g]iven the epidemiological findings showing that

[Dixie Dew Products, Inc.'s] food products are a likely source of an outbreak of *E. coli* O157:H7 and the current conditions of the facility,” the company’s products have a “reasonable probability of causing serious adverse health consequences or death to humans or animals.”

***E. coli* O157:H7**

18. *E. coli* is an archetypal commensal bacterial species that lives in mammalian intestines. *E. coli* O157:H7 is one of thousands of serotypes *Escherichia coli*. The combination of letters and numbers in the name of the *E. coli* O157:H7 refers to the specific antigens (proteins which provoke an antibody response) found on the body and tail or flagellum respectively and distinguish it from other types of *E. coli*. Most serotypes of *E. coli* are harmless and live as normal flora in the intestines of healthy humans and animals. The *E. coli* bacterium is among the most extensively studied microorganism. The testing done to distinguish *E. coli* O157:H7 from its other *E. coli* counterparts is called serotyping. Pulsed-field gel electrophoresis (PFGE), sometimes also referred to as genetic fingerprinting, is used to compare *E. coli* O157:H7 isolates to determine if the strains are distinguishable. A technique called multilocus variable number of tandem repeats analysis (MLVA) is used to determine precise classification when it is difficult to differentiate between isolates with indistinguishable or very similar PFGE patterns.

19. *E. coli* O157:H7 was first recognized as a pathogen in 1982 during an investigation into an outbreak of hemorrhagic colitis associated with consumption of hamburgers from a fast food chain restaurant. Retrospective examination of more than three thousand *E. coli* cultures obtained between 1973 and 1982 found only one (1) isolation with serotype O157:H7, and that was a case in 1975. In the ten (10) years that followed, there were approximately thirty (30) outbreaks recorded in the United States. This number is likely misleading, however, because *E. coli* O157:H7 infections did not become a reportable disease in any state until 1987 when Washington became

the first state to mandate its reporting to public health authorities. As a result, only the most geographically concentrated outbreak would have garnered enough notice to prompt further investigation.

20. *E. coli* O157:H7's ability to induce injury in humans is a result of its ability to produce numerous virulence factors, most notably Shiga-like toxins. Shiga toxin (Stx) has multiple variants (e.g. Stx I, Stx2, Stx2c), and acts like the plant toxin ricin by inhibiting protein synthesis in endothelial and other cells. Shiga toxin is one of the most potent toxins known. In addition to Shiga toxins, *E. coli* O157:H7 produces numerous other putative virulence factors including proteins, which aid in the attachment and colonization of the bacteria in the intestinal wall and which can lyse red blood cells and liberate iron to help support *E. coli* metabolism.

21. *E. coli* O157:H7 evolved from enteropathogenic *E. coli* serotype O55:H7, a cause of non-bloody diarrhea, through the sequential acquisition of phage-encoded Stx2, a large virulence plasmid, and additional chromosomal mutations. The rate of genetic mutation of *E. coli* O157:H7 indicates that the common ancestor of current *E. coli* O157:H7 clades likely existed some 20,000 years ago. *E. coli* O157:H7 is a relentlessly evolving organism, constantly mutating and acquiring new characteristics, including virulence factors that make the emergence of more dangerous variants a constant threat. The CDC has emphasized the prospect of emerging pathogens as a significant public health threat for some time.

22. Although foods of a bovine origin are the most common cause of both outbreaks and sporadic cases of *E. coli* O157:H7 infections, outbreak of illnesses have been linked to a wide variety of food items. For example, produce has, since at least 1991, been the source of substantial numbers of outbreak-related *E. coli* O157:H7 infections. Additional vehicles for *E. coli* O157:H7 outbreaks have included unpasteurized juices, yogurt, dried salami, mayonnaise, raw milk, game

meats, sprouts, and raw cookie dough.

23. According to a recent study, an estimated 93,094 illnesses are due to domestically acquired *E. coli* O157:H7 each year in the United States. Estimates of foodborne acquired *E. coli* O157:H7 cases result in 2,138 hospitalizations and 20 deaths annually. The colitis caused by *E. coli* O157:H7 is characterized by severe abdominal cramps, diarrhea that typically turns bloody within twenty-four (24) hours, and sometimes fevers. The incubation period-which is to say the time from exposure to the onset of symptoms-in outbreaks is usually reported as three (3) to four (4) days, but may be as short as one (1) day or as long as ten (10) days. Infection can occur in people of all ages but is most common in children. The duration of an uncomplicated illness can range from one (1) to twelve (12) days. In reported outbreaks, the rate of death is 0-2%, with rates running as high as 16-35% in outbreaks involving the elderly, like those have occurred at nursing homes.

24. What makes *E. coli* O157:H7 remarkably dangerous is its very low infectious dose, and how relatively difficult it is to kill these bacteria. As few as twenty (20) organisms may be sufficient to infect a person and, as a result, possibly kill them. And unlike generic *E. coli*, the O157:H7 serotype multiplies at temperatures up to 44°F, survives freezing and thawing, is heat resistant, grows at temperatures up to 111°F, resists drying, and can survive exposure to acidic environments.

25. And, finally, to make it even more of a threat, *E. coli* O157:H7 bacteria are easily transmitted by person-to-person contact. There is also the serious risk of cross-contamination between raw meat and other food items intended to be eaten without cooking. Indeed, a principle and consistent criticism of the USDA *E. coli* O157:H7 policy is the fact that it has failed to focus on the risks of cross-contamination versus that posed by so-called improper cooking. With this pathogen, there is ultimately no margin of error. It is for this precise reason that the USDA has

repeatedly rejected calls from the meat industry to hold consumers primarily responsible for *E. coli* O157:H7 infections caused, in part, by mistakes in food handling or cooking.

Hemolytic Uremic Syndrome (HUS)

26. *E. coli* O157:H7 infections can lead to a severe, life-threatening complication called hemolytic uremic syndrome ("HUS"). HUS accounts for the majority of the acute and chronic illness and death caused by the bacteria. HUS occurs in 2-7% of victims, primarily children, with onset five (5) to ten (10) days after diarrhea begins. It is the most common cause of renal failure in children. Approximately half of the children who suffer HUS require dialysis, and many of those who survive have long-term renal impairment. The same number suffers severe brain damage. While somewhat rare, serious injury to the pancreas, resulting in death or the development of diabetes, can also occur. There is no cure or effective treatment for HUS. And, tragically, as too many parents can attest, children with HUS often die.

27. HUS is believed to develop when the toxin from the bacteria, known as Shiga-like toxin (SLT), enters the circulation through the inflamed bowel wall. SLT, and most likely other chemical mediators, attach to receptors on the inside surface of blood vessel cells (endothelial cells) and initiate a chemical cascade that results in the formation of tiny thrombi (blood clots) within these vessels. Some organs seem more susceptible, perhaps due to the presence of increased numbers of receptors, and include the kidney, pancreas, and brain. By definition, when fully expressed, HUS presents with the triad of hemolytic anemia (destruction of red blood cells), thrombocytopenia (low platelet count), and renal failure (loss of kidney function).

28. As already noted, there is no known therapy to halt the progression of HUS. HUS is a frightening complication that even in the best American centers has a notable mortality rate. Among survivors, many will suffer end stage renal disease (ESRD) with the resultant need for

future dialysis or transplantation. Other long-term problems include the risk for hypertension, proteinuria (abnormal amounts of protein in the urine that can portend a decline in renal function), and reduced kidney filtration rate. All that can be said for certain is that HUS causes permanent injury, including loss of kidney function, and it requires a lifetime of close medical monitoring.

J. G.'s Consumption of I.M. Healthy SoyNut Butter, and/or other The SoyNut Butter Company Products Manufactured by Dixie Dew Products, Inc., and *E. coli* O157:H7 Infection.

29. Plaintiffs purchased Defendant's SoyNut Butter and/or other products manufactured, distributed, and/or sold by The SoyNut Butter Company and/or Dixie Dew Products, Inc. for J. G. to eat, as he has a peanut allergy. The products, manufactured and sold by Defendant under SoyNut Butter's brand name, were contaminated with *E. coli* O157:H7. J. G. consumed Defendants' contaminated products in the days preceding his *E. coli* O157:H7 diagnosis.

30. On or about March 10, 2017, J. G. developed watery diarrhea and severe abdominal pain. Within a day or so, J. G.'s symptoms worsened and he developed bloody diarrhea. J. G.'s parents took him to Lakewood Ranch Medical Center Emergency Room for medical treatment.

31. J. G. was ultimately diagnosed with an *E. coli* O157:H7 infection.

32. J. G. continues to recover and faces uncertain future medical complications.

CAUSES OF ACTION

**COUNT I
(Strict Product Liability)**

33. Plaintiffs incorporate the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

34. Defendant manufactured, distributed, and sold the adulterated SoyNut Butter products that injured Plaintiff.

35. Defendant manufactured a food product, including SoyNut Butter products, for sale to the

public.

36. Food that is contaminated by *E. coli* O157:H7 is unsafe when put to the use reasonably foreseeable considering the nature of the product. Namely, *E. coli* O157:H7 contaminated food is unfit for human consumption.

37. The I.M. Healthy brand SoyNut Butter and/or other The SoyNut Butter Company products that Plaintiffs purchased, and that J. G. consumed, were contaminated with *E. coli* O157:H7 when it left the control of Defendant. J. G.'s consumption of the contaminated food caused him to become infected by *E. coli* O157:H7 and to suffer injuries as a direct and proximate result of that consumption.

38. Defendant is strictly liable to Plaintiffs for the harm proximately caused by the manufacture and sale of an unsafe and defective food product.

COUNT II
(Negligence)

39. Plaintiffs incorporate the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

40. Defendant designed, manufactured, distributed, and sold I.M. Healthy brand SoyNut Butter and/or other The SoyNut Butter Company products that were contaminated with *E. coli* O157:H7, a deadly pathogen.

41. Defendant owed a duty to all persons who purchased and consumed its product, including Plaintiff, to manufacture and sell SoyNut Butter and/or other The SoyNut Butter Company products that were safe to eat, that were not adulterated with deadly pathogens, like *E. coli* O157:H7, and that were not in violation of applicable food and safety regulations. Defendant breached this duty.

42. Defendant owed a duty to all persons who purchased and consumed its products, including

Plaintiff, to ensure that any representations regarding the certifications its products had undergone prior to distribution and sale were made with reasonable care. Defendant breached this duty.

43. Defendant had a duty to comply with all statutes, laws, regulations, or safety codes pertaining to the manufacture, distribution, storage, and sale of its food products, but failed to do so, and was therefore negligent. Plaintiffs were among the class of persons designed to be protected by these statutes, laws, regulations, safety codes, or provision pertaining to the manufacture, distribution, storage, and sale of similar food products.

44. Defendant breached the duties owed to the ultimate consumers of I.M. Healthy brand SoyNut Butter and/or other The SoyNut Butter Company products by committing acts and omissions of negligence, including, but not limited to the following:

- a. Failed to adequately maintain or monitor the sanitary conditions of its products, premises, equipment and employees, and the products, premises, equipment, and employees of other entities in the supply chain of the subject SoyNut Butter and/or other The SoyNut Butter Company products;
- b. Failed to properly operate its facilities and equipment in a safe, clean, and sanitary manner;
- c. Failed to apply its food safety policies and procedures to ensure the safety and sanitary conditions of its food products, premises, and employees;
- d. Failed to apply food safety policies and procedures that met industry standards for the safe and sanitary production of food products, and the safety and sanitary condition of its premises and employees;
- e. Failed to prevent the transmission of *E. coli* O157:H7 to consumers of its SoyNut Butter and/or other The SoyNut Butter Company products;

- f. Failed to properly train its employees and agents how to prevent the transmission of *E. coli* O157:H7 on its premises, from its facility or equipment, or in its food products;
 - g. Failed to properly supervise its employees and agents to prevent the transmission of *E. coli* O157:H7 on its premises, from its facility or equipment, or in its food products.
 - h. Failed to test its SoyNut Butter and/or other The SoyNut Butter Company products for microbial pathogens, like *E. coli* O157:H7.
45. Defendant had a duty to comply with all statutory and regulatory provisions that pertained or applied to the manufacture, distribution, storage, labeling, and sale of its food products. Defendant breached this duty.
46. Defendant owed a duty to Plaintiffs to use reasonable care in the manufacture, distribution, and sale of its food products, to prevent contamination with *E. coli* O157:H7. Defendant breached this duty.
47. Plaintiffs' injuries proximately and directly resulted from the negligence of Defendant, and from Defendant's violations of statutes, laws, regulations, and safety codes pertaining to the manufacture, distribution, storage, and sale of food.

COUNT III
(Breach of Warranty)

48. Plaintiffs incorporate the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.
49. By offering SoyNut Butter and/or other The SoyNut Butter Company products for sale to the public, Defendant impliedly warranted that such SoyNut Butter and/or other The SoyNut Butter Company products were safe to eat, that it was not adulterated with a deadly pathogen, and that the SoyNut Butter and/or other The SoyNut Butter Company products had been safely prepared under sanitary conditions.

50. Defendant breached the implied warranties about the food they manufactured and sold to Plaintiffs, which was consumed by J. G., causing Plaintiff's injuries and losses.

51. Plaintiffs' injuries proximately and directly resulted from Defendant's breach of implied warranties, and Plaintiffs are thus entitled to recover for all actual, consequential, and incidental damages that flow directly and in a foreseeable fashion from these breaches.

COUNT IV
(Parent's Right to Reimbursement)

52. Plaintiffs incorporate the preceding paragraphs of this Complaint, by this reference, as if each of these paragraphs were set forth here in its entirety.

53. As the direct and proximate result of the Defendant's acts and omissions, Plaintiffs suffered ordinary, incidental, and consequential damages as would be anticipated to arise under the circumstances, which shall be fully proven at the time of trial.

54. Illinois Law entitles parents to file a cause of action to recover reimbursement for expenses they incur that relate to an injured minor child, including medical expenses, as governed by the Illinois Family Expense Act 750 ILCS 65115 [See *Dewey v. Zack*, 272 Ill.App.3d 742, 746, 651 N.E.2d 643 (2nd Dist. 1995)].

55. Plaintiffs incurred multiple medical, medicinal, and laboratory expenses due to the necessary testing, diagnosis and treatment for the minor child J. G.'s *E. coli* O157:H7 infection, including medical bills, lost wages, and additional expenses.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray as follows:

1. That the Court award Plaintiffs judgment against Defendant for damages.
2. That the Court award all such other sums as shall be determined to fully and fairly compensate the Plaintiffs for all general, special, incidental and consequential damages

incurred, or to be incurred, by Plaintiffs as the direct and proximate result of the acts and omissions of the Defendant;

3. That the Court award Plaintiffs costs, disbursements and reasonable attorneys' fees incurred;
4. That the Court award Plaintiffs the opportunity to amend or modify the provisions of this Complaint as necessary or appropriate after additional or further discovery is completed in this matter, and after all appropriate parties have been served; and
5. That the Court award such other and further relief as it deems necessary and proper in the circumstances.

JURY TRIAL DEMAND

Plaintiffs demand trial by jury on all issues raised herein.

Dated: May 24, 2017.

Respectfully submitted,

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